**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA,

Plaintiff,

vs.

INNOVATIVE BIODEFENSE, INC. et al,

Defendants.

CASE NO. SA CV 18-0996-DOC (JDEx)

**FINDINGS OF FACT AND CONCLUSIONS OF LAW AND ORDER DENYING MOTION FOR RECONSIDERATION [145]**

## I. INTRODUCTION

A bench trial on this matter was held on from December 16 through 20, 2019, and January 22 through 23, 2020. Closing arguments were heard on March 2, 2020.

This is a statutory injunction proceeding in which the United States seeks to permanently enjoin Innovative BioDefense, Inc. ("IBD"), Dr. Colette Cozean ("Cozean"), and Hotan Barough ("Barough") (collectively, "Defendants") from violating the Federal Food, Drug, and Cosmetic Act ("FDCA"). In the summary judgment ruling, this Court held that Defendants violated the FDCA as a matter of law. [Order Granting in Part Pl.'s Mot. for Summ. J. & Den. Def.'s Mot. for Summ. J. at 14, Dkt. 124 ("Order")]. Accordingly, the only issues left to be addressed at trial were Defendants' affirmative defenses of laches and unclean hands and the appropriate scope of injunctive relief. [*Id*. at 18 & n.6].

Defendants allege the following affirmative defenses:

1. Laches
2. Unclean Hands

The Court issues the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52. To the extent that any findings of fact are included in the conclusions of law section, they shall be deemed findings of fact, and to the extent that any conclusions of law are included in the findings of fact section, they shall be deemed conclusions of law.

## II. FINDINGS OF FACT

### A. Background

1. Dr. Colette Cozean founded IBD in June 2011 and serves as the company's President and CEO. [12/20/2019 Trans. Vol. I at 7:24–8:3, 10:23–11:1].
2. One of IBD's first investors was Dr. Cozean's son, Jesse Cozean, who invested $50,000 in the company and became IBD's Vice President of Research and

Development. [*Id.* at 18:5–17; 1/22/2020 Trans. Vol. III at 19:12–14].

3. Through IBD, Dr. Cozean organized a group of 40 investors to spend $4 million and acquire a product line called Zytrel. [12/20/2019 Trans. Vol. I at 11:18–12:13, 14:8–10].

4. Zytrel had an antiseptic hand sanitizer with 73% alcohol and .18% benzethonium chloride ("BZT"), as well as a lotion containing BZT and a soap. The company that made Zytrel told Dr. Cozean and her investors that there were other Zytrel products as well, but that turned out to be untrue. [*Id.* at 12:20–25; Ex. 77 at 4].

5. IBD purchased the Zytrel product line in June 2011. [12/20/2019 Trans. Vol. I at 16:19–16:21].

6. The Zylast product line includes, or has included, an antiseptic hand sanitizer, lotion, foaming soap, and surgical scrub. [*Id.* at 17:2–17:6; Ex. 889]. The Zylast antiseptic contains 76% alcohol, and the Zylast lotion contains 0.2% BZT as an "inactive" ingredient. [1/22/2020 Trans. Vol. III at 43:20–25; Ex. 889].

7. Hand sanitizers are over-the-counter ("OTC") antimicrobial drugs. [12/17/2019 Trans. Vol. 1 at 12:19–12:22].

8. OTC drugs do not require the oversight of a health care practitioner, are available for sale directly to consumers, have a low potential for abuse, and are generally low risk. [*Id.* at 12:1–12:8; 1/23/2020 Trans. Vol. III at 78:6–78:16].

9. OTC drugs are regulated by the OTC Drugs Branch, an office within the Food and Drug Administration, Center for Drug Evaluation and Research ("CDER"). The mission of the OTC Drugs Branch is to protect the public from ineffective and/or unsafe OTC drugs by enforcing the FDCA, including the statute's unapproved new drug provisions. [12/17/2019 Trans. Vol. I at 9:13–9:22; 11:16–11:21].

10. FDA has proposed "monographs" that establish the conditions under which OTC topical antiseptics may be deemed generally safe and effective. [Order Den. Mot. to Dismiss at 4, Dkt. 60]. These non-final monographs do not permit a firm to make

claims in product labeling that suggest or recommend an antiseptic hand sanitizer for use in preventing illness or infection by specific pathogens. *Id.* at 13–14.

11. Some companies make pathogen-specific claims in the labeling of hand sanitizer products, in violation of FDA's monographs, in order to drive sales and obtain market advantage over their competitors. [1/23/2020 Trans. Vol. III at 22:3–10].

**B. 2012 Meeting Between IBD and FDA to Discuss Claims of Efficacy**

12. IBD submitted a request to FDA on April 26, 2012, for a Pre-Investigational New Drug Application ("pre-IND") meeting to discuss the development plan for the Zytrel hand sanitizer and surgical scrub. [Ex. 77 at 4].

13. The purpose of a pre-IND meeting is to generally discuss with FDA the standards that a firm would need to meet, and the testing or investigation that would need to be completed, in order to have a New Drug Application ("NDA") approved by the agency. [1/23/2020 Trans. Vol. II at 70:4–9].

14. IBD's pre-IND meeting took place on June 11, 2012. [Ex. 77 at 2].

15. Dr. Cozean, Jesse Cozean, and Steve Czerwinski attended the pre-IND meeting on behalf of IBD. [*Id*. at 3]. Nineteen individuals from FDA attended the pre-IND meeting, including representatives from CDER's Division of Nonprescription Clinical Evaluation, Division of Nonprescription Regulation Development, Office of New Drug Quality Assurance, Division of Anti-Infective Products, Division of Biometrics IV, Office of Pharmaceutical Sciences, and Division of Antiviral Products. [*Id*. at 2–3].

16. Prior to the meeting, IBD provided the agency with a list of questions, including questions regarding claims of effectiveness against Methicillin-resistant Staphylococcus aureus ("MRSA"), nosocomial infections, and norovirus, as well as information regarding studies that the firm had conducted. [*Id*. at 4–12; 3/2/2020 Trans. Vol. I at 8:1–6].

17. FDA told IBD that claims relating to the prevention of infection, including effectiveness in preventing infection by MRSA, would not be covered by applicable FDA monographs and should be developed under an NDA. FDA also told IBD that (1) such claims would require clinical studies, (2) the studies IBD had submitted were insufficient for making claims of effectiveness against MRSA, nosocomial infections, and norovirus, and (3) consumer studies might be required to determine whether consumers could understand the intended claim. Additionally, FDA "strongly recommended" that IBD submit testing protocols for agency review and comment. [Ex. 77 at 8–11].

18. As an "Action Item" listed in the minutes of the pre-IND meeting, FDA reiterated its recommendation that IBD submit testing protocols to FDA for review and comment before commencing any product studies. [*Id*. at 16].

19. In spite of this, IBD has never submitted any testing protocols to FDA for review and comment. [1/22, 2020 Trans. Vol. III at 51:17–20; 1/22/2020 Trans. Vol. IV at 9:14–9:18, 13:9–12].

**C. Zylast Complaints**

20. On or around November 20, 2013, approximately seventeen months after the pre-IND meeting, CDER received a letter complaining about claims in the Zylast products' labeling suggesting that Zylast is effective in preventing norovirus, nosocomial infections, and influenza. [Ex. 646 at 1, 3; *see also* 3/2/2020 Trans. Vol. I at 29:2–9].

21. Heath Harley, a Consumer Safety Officer in the OTC Drugs Branch, was assigned to review the letter. [Ex. 652 at 1–2; 3/2/2020 Trans. Vol. I at 29:2–9].

22. In regulating the OTC drug industry, it is common for the Branch to receive complaint letters about a particular OTC drug and then independently evaluate whether the drug appears to comply with the FDCA and agency regulations. [12/17/2019 Trans. Vol. I at 18:8–18:11; 12/18/2019 Trans. Vol. III at 16:24–17:1].

23. Heath Harley reviewed the November 20, 2013 letter and the Zylast products' websites on or around April 4, 2014. [Ex. 652 at 1; 12/18/2019 Trans. Vol II at 99:14–22; 12/18/2019 Trans. Vol III at 18:10–19:2].

24. He concluded that the labeling for the Zylast products contained statements that were not covered by applicable FDA monographs (including statements relating to MRSA) but did not recommend regulatory action at that time due to competing agency priorities. Mr. Harley did, however, recommend that the Zylast products be catalogued for future regulatory action through an initiative by CDER's Office of Unapproved Drugs and Labeling Compliance. [Ex. 652 at 1; 12/18/2019 Trans. Vol. III at 18:10–21:15].

25. In response to Heath Harley's recommendation in April 2014, Mr. Harley's immediate supervisor concurred, further noting that the Zylast products would be good candidates for alternative enforcement strategies such as FDA's Health Fraud Group's serious disease alternate enforcement strategy, which was under development. [Ex. 652 at 1; 12/18/2019 Trans. Vol. III at 21:1–21:23].

**D. Ebola Outbreak and the "Grand Challenge"**

26. In March 2014, the World Health Organization announced that there was a rapidly evolving outbreak of the Ebola virus in West Africa. The outbreak would eventually kill 11,323 people. [Ex. 146 at 2, 6; 12/17/2019 Trans. Vol. I at 13:13–13:18].

27. Accordingly, in a statement on August 14, 2014, FDA warned the public that there were no FDA-approved drugs to prevent Ebola and encouraged consumers to report any such claims to the agency. [Ex. 284 at 1–2].

28. "Fighting Ebola: A Grand Challenge for Development" is a grant program run by the U.S. Agency for International Development ("USAID") that, in 2014, sought to provide financial and/or other support to facilitate the testing of products that could aid healthcare workers combatting Ebola in West Africa. [Ex. 503 at 1].

29. On December 12, 2014, USAID announced that IBD had been nominated for a grant under the program. Through it, IBD would receive $250,000 for product testing of the Zylast antiseptic, which IBD said could provide up to six hours of protection against pathogens and serve as an effective anti-microbial barrier to viral transmission. [*Id.*; 12/20/2019 Trans. Vol. I at 39:7, 79:9–11].

30. When applying for the $250,000 grant, IBD told USAID that the Zylast products were being sold in compliance with FDA's monographs. [12/20/2019 Trans. Vol. II at 21:20–22:2; 12/18/2019 Trans. Vol. I at 95:21–23].

31. IBD leveraged its award through the "Fighting Ebola: A Grand Challenge for Development" program to drive sales of Zylast and promote the products to American consumers. For example, On December 11, 2014, Jesse Cozean asked Hotan Barough to create the promo code, "FightingEbola." [1/22/2020 Trans. Vol. IV at 51:24–52:1; Ex. 28 at 1]. Use of the "FightingEbola" promo code gave customers a 10% discount on their purchase of Zylast at zylastdirect.com. [*Id.*; Ex. 219 at 1].

32. "FightingEbola" was not the only promo code that Defendants created around this time that suggested Zylast for use in preventing infection by specific diseases. On February 16, 2015, Jesse Cozean asked Hotan Barough to create the promo code, "StopNorovirus," which would give customers a 10% discount at zylastdirect.com. [Ex. 25 at 1; 1/22/2020 Trans. Vol. IV at 52:10–12; 12/19/2019 Trans. Vol. I at 32:20–33:2].

33. On or around December 24, 2014, CDER received another complaint letter about Zylast. [Ex. 636; 12/17/2019 Trans. Vol. I at 17:14–18:14]. This new letter attached the earlier November 7, 2013 complaint letter (Ex. 646). Commander Tina Smith—then a team-lead in the OTC Drugs Branch—was assigned to review the letters. [Ex. 566 at 2; 12/17/2019 Trans. Vol. I at 17:14–18:14]

34. Commander Smith had recently returned from domestic deployment as part of the United States Public Health Service's ("USPHS") response to the Ebola outbreak.

She conducted an independent review of Defendants' websites and was particularly concerned about the disease-specific claims she found regarding Zylast, including claims that Zylast could help prevent infection by Ebola. [12/17/2019 Trans. Vol. I at 16:14–17:13, 24:5–11, 25:18–26:1]. Accordingly, Commander Smith recommended that FDA issue a Warning Letter to IBD. [*Id*. at 21:17–22:5; Ex. 566 at 1–2].

35. Defendants believe that the recommendation to issue a warning letter was in response to complaints lodged by counsel for GOJO Industries. However, the Court finds that Commander Smith's review of Defendants' websites provided a different impetus for issuing a warning: IBD was still not in compliance with the FDCA.

36. On February 4, 2015, USAID contacted FDA's Center for Devices and Radiological Health seeking information about the Zylast products and "what additional testing may be necessary" to use the products against Ebola. [Ex. 635 at 4–6; 12/18/2019 Trans. Vol. I at 101:20–25].

37. USAID did not tell FDA that the Zylast products were already being sold to American consumers or that IBD was already making claims that Zylast provided persistent protection against infection by Ebola. [Ex. 635].

38. The Center for Devices and Radiological Health forwarded the USAID inquiry to CDER's Division of Antiviral Products—one of the groups that assists with the regulatory approval process and which participated in IBD's pre-IND meeting in June 2012. [*Id*. at 4; Ex. 77 at 3; 12/17/2019 Trans. Vol. I at 54:9–14].

39. On or around March 17, 2015, Heath Harley contacted USAID to learn more about the "Fighting Ebola: A Grand Challenge for Development" program, and whether IBD had, in fact, been awarded a grant through the program for the Zylast products, or whether the grant had been awarded to an experimental product that was not being marketed at that time. [12/17/2019 Trans. Vol. I at 48:2–10; Ex. 750 at 85, 90].

**E. IBD's Regulatory Status Call with FDA**

40. The OTC Drugs Branch did not immediately issue a Warning Letter to IBD. Instead, in light of the "Fighting Ebola: A Grand Challenge for Development" program, the Branch sought to obtain IBD's voluntary compliance by communicating with the firm directly about its unlawful conduct through a regulatory status call. [12/17/2019 Trans. Vol. I at 42:23–43:13, 51:10–13].

41. Five days before the scheduled regulatory status call, on March 26, 2015, Heath Harley documented that IBD made the following disease-specific claims about Zylast on zylast.com, in addition to the Ebola-related claims previously found:

    a. "Zylast has been shown to be more than 100 times more effective than alcohol alone, killing 99.97% of Norovirus on contact!";

    b. "Zylast was tested against MRSA out to six hours after application, with both products destroying more than 90% of MRSA one hour after they had been applied"; and

    c. "Zylast technology was shown to kill more than 99.99% of 25 different, FDA-specified germs within 15 seconds including . . . E. coli . . . [and] influenzae."

    [Ex. 163 at 1–2].

42. The regulatory status call between FDA and representatives of IBD occurred on March 31, 2015. [Ex. 650 at 1; 12/17/2019 Trans. Vol. I at 51:20–24].

43. On the call, Anuj Shah informed IBD that zylast.com contained claims that were not covered under any applicable FDA monograph, including claims of effectiveness against specific pathogens. [Ex. 149 at 3].

44. Towards the end of the call, Marc Sanchez, counsel for Defendants in this action, summarized potential ways the company could address FDA's regulatory concerns: remove all pathogen-specific claims from the Zylast products' labeling, including from zylast.com, and either (1) petition the agency to be allowed to make new claims

or suggest new uses or (2) submit an NDA. [*Id*. at 4].

45. During the call, IBD requested permission to continue the firm's "interim" marketing of the Zylast products and make disease-specific claims while the firm pursued an NDA. [*Id*. at 3; 12/18/2019 Trans. Vol. III at 42:7–11].

46. FDA responded that "interim" marketing in violation of the FDCA was not allowed. [*Id*. at 4; 12/18/2019 Trans. Vol. III at 42:7–19].

47. FDA asked IBD to inform the agency within 10 days what it planned to do to come into compliance. IBD asked for additional time to respond, and FDA agreed to provide IBD an extra week to prepare its response. [*Id*. at 3–4].

48. Attorney Sanchez sent IBD's response letter on or around April 8, 2015. In the response, IBD did not identify any corrective action it would take to address its unlawful conduct. Instead, IBD argued that "it is difficult to view the pathogen specific references to clinical data [being made in the Zylast products' labeling] as prohibited marketing claims." IBD also suggested that FDA was engaging in rulemaking through enforcement. [Ex. 150 at 1, 6; 12/17/2019 Trans. Vol. I at 62:12–63:2].

49. Because IBD's letter did not to the agency's concerns, acknowledged no wrongdoing, and described no corrective actions to be taken by the company, FDA personnel found it unlikely that IBD would come into prompt, adequate, and voluntary compliance. [Ex. 150; 12/17/2019 Trans. Vol. I at 62:7–11].

**F. IBD Continues Making Disease-Specific Statements.**

50. After the regulatory status call, Elizabeth Miller—then the Director of CDER's Division of Nonprescription Drugs and Health Fraud—had a one-on-one phone call with Attorney Sanchez regarding the Zylast products. [12/17/2019 Trans. Vol. I at 68:21–69:3].

51. After the regulatory status call and Elizabeth Miller's call with Attorney Sanchez,

FDA personnel concluded that additional meetings or calls would be unproductive for obtaining IBD's voluntary compliance. [12/17/2019 Trans. Vol. I at 73:10–74:3]. Meanwhile, Defendants continued to suggest the Zylast products for use in preventing illness and infection by specific diseases, which FDA documented and on which Defendants' customers relied. [Ex. 182 at 1–2; 12/18/2019 Trans. Vol. III at 42:7–46:17].

52. On April 28, 2015, Heath Harley documented the following additional disease-specific claims being made about Zylast on zylastdirect.com:

a. "Zylast kills more than 99% of Rhinovirus, the highly contagious 'common cold' on contact!"; and

b. "Zylast kills influenza, 'the flu' and killed 99.99% of the H1N1 strain in 15 seconds!"

[Ex. 182 at 1–2; 12/18/2019 Trans. Vol. III at 42:7–46:17].

## G. IBD Proposes Adding a Simple Disclaimer to zylast.com Instead of Removing Pathogen-Specific Claims

53. Attorney Sanchez sent FDA a letter dated May 15, 2015, suggesting that as an "interim change[]," IBD would add a disclaimer to its marketing literature and zylast.com stating, "This information is for educational purposes only. The FDA does not approve and Zylast does not make claims of effectiveness against specific bacteria or viruses." [Ex. 151 at 1–2; 12/17/2019 Trans. Vol. I at 69:25–70:23].

54. FDA responded to Attorney Sanchez's communication via letter dated June 15, 2015, stating that "the proposed disclaimer does not adequately address[] our concerns with respect to consumer-directed claims demonstrating intended use against serious-disease causing pathogens such as Methicillin-resistant Staphylococcus Aurus (MRSA) and H1N1 flu virus." [Ex. 152 at 1]. This was because, despite use of such a disclaimer, consumers could still get a false impression from Defendants' numerous

disease-specific claims that Zylast is effective at preventing such illnesses and infections. [12/17/2019 Trans. Vol. I at 70:21–71:7].

**H. IBD and Dr. Cozean Receive a Warning Letter Regarding Potential Violations of the FDCA and Federal Trade Commission Act**

55. FDA and the FTC jointly issued a Warning Letter dated June 30, 2015, to IBD and Dr. Cozean. [Ex. 93 at 1; 12/17/2019 Trans. Vol. I at 77:18–77:20].

56. FDA's practice is to issue a Warning Letter to the party that the agency believes is most responsible for the product at issue, on the basis that the most responsible party is capable of bringing the product promptly and adequately into compliance with the FDCA. [*Id*. at 76:25–77:4].

57. The joint FDA/FTC Warning Letter was issued to IBD and Dr. Cozean, the firm's President and CEO, because FDA believed they were the parties most responsible for the Zylast products. [*Id*. at 76:18–24].

58. The Warning Letter notified IBD and Dr. Cozean that disease-specific claims being made about the Zylast products on zylast.com, zylastdirect.com, the ZylastXP Facebook page, and the ZylastXP Twitter feed demonstrated that the Zylast products were intended to be effective against serious disease-related pathogens, such as MRSA, norovirus, H1N1, and Ebola. Because such claims are not covered by any applicable FDA monograph, and because the Zylast products are not generally recognized as safe and effective for all of their intended uses, the products were unapproved new drugs. [Ex. 93 at 1–5].

59. The Warning Letter warned that failure to correct the cited violations could result in legal action by the Government without further notice, including pursuit of an injunction. [*Id*. at 6–7].

60. Heath Harley was the primary author of the FDA portions of the Warning Letter. [12/17/2019 Trans. Vol. I at 80:20–81:5, 83:13–15; 12/18/2019 Trans. Vol. III at

46:17–19].

61. Raymond Brullo, a Compliance Safety Officer in FDA's Los Angeles District Office, was responsible for sending a hard copy of the Warning Letter to IBD and Dr. Cozean. [12/19/2019 Trans. Vol. II at 30:5, 30:22–24, 32:19–21]. This was Dr. Brullo's primary role with respect to FDA's work on the Zylast products. [*Id*. at 30:22–24]. He had no role in drafting the Warning Letter or in deciding to issue a Warning Letter to IBD and Dr. Cozean. [12/17/2019 Trans. Vol. I at 84:4–9; 12/19/2019 Trans. Vol. II at 32:22–33:4, 42:12–16; *see also* Ex. 648 at 1].

62. In the Warning Letter, Raymond Brullo was listed as the point of contact within FDA if IBD had questions. [Ex. 93 at 7]. This accorded with FDA's general practice of listing a District Compliance Safety Officer as the point of contact in a Warning Letter for purposes of receiving correspondence from a firm. [12/19/2019 Trans. Vol. II at 34:2–12].

63. Approximately one week later, in a letter dated July 6, 2015, USAID rescinded the Zylast products' nomination for a grant under the "Fighting Ebola: A Grand Challenge for Development" program. USAID stated that, "[i]n light of FDA findings that the product requires more extensive development and testing before it can be considered compliant with the Tentative Final Monograph, it is no longer a good fit for the Fighting Ebola program, which is focused on identifying near-term solutions to the Ebola epidemic." [Ex. 270 at 1].

## I. IBD's Reaction to the Letter

64. Attorney Sanchez wrote to FDA regarding the Warning Letter in letters dated July 6 and 16, 2015. [*See* Ex. 153].

65. In his communications to FDA on July 6 and 16, 2015, Attorney Sanchez did not provide any of the information that FDA requested in the Warning Letter. He identified and provided no documentation of any specific steps already taken or being

taken by IBD to correct the FDCA violations noted in the Warning Letter, or any steps the firm would take to prevent future violations. Nor did Attorney Sanchez indicate that IBD had decided to stop manufacturing or marketing the Zylast products. [*Id.*; *see also* Ex. 93 at 6–7].

66. Instead, Attorney Sanchez asked FDA to refrain from publishing the Warning Letter on the agency's website. In his letters, Attorney Sanchez went on to accuse FDA of alleged improprieties and misconduct, arguing that "there is a strong inference Gojo influenced and/or aided in developing the Warning Letter"; claiming the Warning Letter "mimic[ked] the Gojo complaint [filed in the Southern District of New York against IBD] in form and substance"; and contending that the Warning Letter "selectively edits statements to remove vital context." [Ex. 153 at 1, 5, 6].

67. FDA believed IBD's reaction to the Warning Letter was unusual. Generally, FDA is "very successful in achieving voluntary compliance with a Warning Letter." Indeed, of all the matters on which Commander Smith has worked, this is the only one that has gone to litigation because the agency could not obtain voluntary compliance by the firm. [12/17/2019 Trans. Vol. I at 22:20–23:4].

**J. Defendant's Contention that GOJO Industries Inc. Enlisted the FDA to "Wage War" Against IBD**

68. GOJO Industries, the maker of Purell, is the market leader in the hand sanitizer industry. [1/22/2020 Trans. Vol. II at 5:9–18].

69. GOJO's law firm, Hyman Phelps, employs eleven individuals who formerly worked for the FDA out of the nineteen individuals in its FDA practice. [Hyman Dep. Tr. at 59:11–60:14; Ex. 559].

70. The law firm's named director, founding member, and GOJO counsel who most frequently contacted the FDA regarding IBD, Paul Hyman, began his career at the FDA. [Hyman Dep. Tr. at 10:14–18, 12:13–13:1].

71. Defendants believe that GOJO was threatened by IBD, and that GOJO established an "anti-Zylast task force" regarding Zylast products that met weekly "to decide how they could best eliminate the threat that Zylast posed to them." This group included 15 to 20 high-level individuals at GOJO Industries, including both in-house and outside counsel, together with a regulatory attorney and litigator. [1/22/2020 Trans. Vol. II at 7:22–8:8, 9:12–11:13].

72. On April 15, 2015, GOJO Industries sued IBD, alleging that IBD engaged in false advertising and deceptive business practices. [Ex. 518; 1/22/2020 Trans. Vol. I at 53:3–14].

73. On August 10, 2017, GOJO filed suit against Hotan Barough. [*See* Complaint, *GOJO Indus., v. Hotan Barough*, No. 8:17-cv-01382-DOC (C.D. Cal. Aug. 10, 2017); 1/23/2020 Trans. Vol. II at 12:2–13].

74. Meanwhile, GOJO's counsel continued to aggressively pressure the FDA to take action against Zylast products throughout 2015. [*See* 1/23/2020 Trans. Vol. II at 14:19–14:23].

75. On February 19, 2015, GOJO's counsel left the FDA a voicemail threatening to take his complaints about IBD "higher up in the agency." [Ex. 613].

76. The next day, on February 20, 2015, Tina Smith instructed Heath Harley to "move forward" with action against IBD. [Ex. 639].

77. On March 13, 2015, GOJO's lawyer wrote the FDA demanding that the FDA take "prompt and decisive regulatory action" against IBD. [Ex. 609].

78. On April 1, 2015, GOJO's lawyer wrote FDA urging the FDA to launch a criminal investigation into IBD. [Ex. 614].

79. On April 10, 2015, GOJO's lawyer left a voicemail for the FDA, about IBD, stating, "You've really got to do something to stop it." [Ex. 556].

80. On the same day, GOJO's lawyer wrote FDA urging "prompt and vigorous action" against IBD. [Ex. 555].

81. On May 13, 2015, GOJO's lawyer wrote to the FDA urging "vigorous regulatory action" against IBD. [Ex. 619].

82. On July 6, 2015, Dr. Brullo characterized the IBD matter as "high profile" because of GOJO's involvement and the civil suit GOJO filed against IBD. [Ex. 648].

**K. At the Same Time, FDA Failed to Take Action Against the Disease-Specific Claims Made by IBD's Competitors, Including GOJO**

83. On April 8, 2015, IBD informed the FDA that competitors were making similar pathogen-specific statements about their products. [Ex. 150].

84. However, IBD was the only hand sanitizer company with a warning letter and the only one sued by DOJ in the past four years. [12/17/2019 Trans. Vol. II at 28:23–30:15].

85. Until the eve of this trial, the FDA failed to act against any other hand sanitizer company for making pathogen-specific statements. [12/17/2019 Trans. Vol. II at 28:7–25 ].

86. During this trial, Commander Smith acknowledged that IBD's competitors are making pathogen-specific statements about their products. [12/17/2019 Trans. Vol. I at 65:11–66:21, 67:2–4; 68:5–10; 69:14–70:25].

87. Heath Harley similarly stated that "too many" companies are making pathogen-specific claims. [12/19/2019 Trans. Vol. I at 81:11–15].

88. During this trial, GOJO's website contained several examples of pathogen-specific statements regarding its products. [Exs. 560, 560-A, 561, 562, 564].

89. GOJO's counsel, Paul Hyman, admitted at his deposition in October 2019 that GOJO's statements about Purell products were improper and in violation of FDA regulations. [Hyman Dep. Tr. at 75:16–76:2].

90. After reviewing several GOJO website statements, Mr. Hyman stated, "If these are on their website, the U.S. website or in the U.S., they would not be in compliance."

[Hyman Dep. Tr. at 90:4–90:10].

91. For example, regarding Exhibit 562—an advertisement for Purell that states, "Kills more than 99 percent of most common germs that may cause illness in a healthcare setting, including MRSA and VRE"—Mr. Hyman stated that this particular claim is improper. [Hyman Dep. Tr. at 75:9–76:2].

92. When the Court asked when GOJO was getting its warning letter, Commander Smith stated as soon as she drafts it and gets it approved. [12/18/2019 Trans. Vol. II at 57:1–4].

93. Despite being aware of pathogen-specific statements by GOJO since 2005, the FDA failed to take any action against GOJO until during this trial, when it finally issued GOJO a Warning Letter in January 2020. [Ex. 301].

94. Due to the FDA's disparity in enforcement, IBD felt singled out. [1/23/2020 Trans. Vol. I at 28:14–24].

95. The Court notes that, though the circumstances surrounding the FDA's lack of enforcement against much bigger players in the market seem suspect, these facts do not remedy the fact that IBD has repeatedly been in violation of the FDCA.

96. However, the Court throughout the trial admonished the FDA for its total lack of enforcement against bigger actors who are arguably causing more harm to consumers. The disparity in enforcement creates a perception of favoritism that, while not impacting this Court's decision about the particular Defendant before this Court, may erode public confidence in the agency.

**L. FDA Decides to Pursue Litigation, and IBD Continues Making Disease-Specific Claims. Hotan Barough Tells Customers that the Issues Raised in the Warning Letter Have Been Resolved.**

97. FDA sent a letter dated August 12, 2015, responding to Attorney Sanchez's July 16, 2015 correspondence on behalf of IBD. FDA noted that IBD had provided no

substantive response to the violations described in the Warning Letter and identified no measures to be implemented by IBD to correct the violations. FDA also reiterated that IBD's failure to correct the violations cited in the Warning Letter could lead to legal action being filed by the Government without further notice. [Ex. 154 at 1–2].

98. In a letter dated August 11, 2015, the FTC responded to Marc Sanchez's July 16, 2015 letter, stating that the agency found IBD's response to be non-responsive. [Ex. 281 at 1].

99. IBD sent no response to FDA's August 12, 2015 letter, and there is no evidence IBD ever responded to the FTC's August 11, 2015 letter. [Ex. 728 at 2].

100. Given IBD's failure to come into voluntary compliance and lack of any substantive response to the violations described in the Warning Letter, CDER recommended that FDA pursue injunctive relief against IBD. The Center believed that IBD and Dr. Cozean would continue to violate the FDCA in the absence of an injunction. [12/17/2019 Trans. Vol. I at 99:19–24].

101. Meanwhile, Hotan Barough received multiple communications from Zylast Direct customers showing that consumers had relied on the disease-specific claims made about Zylast, were aware of the Warning Letter issued to IBD, and felt deceived by the statements Defendants had made about the products. In response, Hotan Barough tried to downplay the significance of the Warning Letter and convince his customers that Zylast was being lawfully marketed. For example:

    a. On or around August 26, 2015, Hotan Barough received an email from a customer stating that she was a recent cancer patient recovering from chemotherapy, had a compromised immune system, and was trying to stay healthy. She said, "I know Zylast kills the norovirus" and asked whether the product would provide persistent protection against infection by norovirus for 6 hours, just like Zylast's purported "6 hours of persistent germ killing." [Ex. 16 at 1–2].

b. Hotan Barough also received an email from a Zylast Direct customer containing a link to the IBD Warning Letter on FDA's website. The customer said, "I just found out you are lieing [sic] about your product" and asked for his order of the Zylast foaming soap and lotion to be cancelled. Ex. 49 at 1. In response, Hotan Barough told the customer that "[m]any prominent manufacturers, including GOJO (the makers of Purell) have received Warning Letters"; "IBD/Zylast has responded to the concerns raised by the FDA in their letter"; and that the Warning Letter "[did] not affect marketability." [Ex. 49 at 1].

**M. FDA Believes IBD Is Still Making Ebola-Related Claims and Thus Refers the Matter to the Department of Justice**

102. In June 2016, FDA referred this matter to the Department of Justice ("DOJ"), requesting that the Department file a complaint for permanent injunction. [12/17/2019 Trans. Vol. II at 6:24–7:2].

103. Between June 2017 and April 2018, DOJ corresponded with counsel for IBD in an attempt to negotiate a resolution short of litigation. Those efforts were unsuccessful. [Ex. 134; Ex. 135; Ex. 136].

104. The Government filed its Complaint for Permanent Injunction on June 6, 2018. [Dkt. 1].

105. Shortly after the Complaint was filed, on July 2, 2018, Amazon.com sent Hotan Barough an email noting that the Zylast products had been identified as making "prohibited claims." The email informed Mr. Barough that the Zylast products would be prohibited for sale on Amazon, and that if he wished for the products to be reinstated, he would need to provide "proof that the Warning Letter has been closed out with the FDA." [Ex. 52 at 1].

106. The Government filed its Amended Complaint for Permanent Injunction on August

27, 2018, adding Hotan Barough as a defendant. [Dkt. 18].

N. **Despite the Filing of the Complaint and Amended Complaint, Defendants Continue Making Disease-Specific Claims about Zylast Throughout the Duration of Litigation**

107. Defendants persisted in claiming that Zylast is effective in preventing infection and illness by specific pathogens, even after the filing of the Government's Complaint and Amended Complaint.

108. On October 31, 2018, Heath Harley documented the following disease specific claims still being made about Zylast on zylastdirect.com:

a. "United States announces that Zylast is one of the winners of the grand challenge to fight ebola"; and

b. "Zylast is 100 times more effective against Norovirus 'the stomach flu.'"

[Ex. 190 at 1; Ex. 192 at 1].

109. On November 6, 2018, Heath Harley documented the following disease specific claims being made about Zylast on zylast.com:

a. "[s]hown to Kill > 99% of Norovirus surrogate";

b. "[s]hown to reduce hospital infections by 23.1%, illness in schools by 39%, and illness outbreaks by almost 90% when used in real-world settings"; and

c. "Zylast Antiseptic is a very exciting new hand sanitizer that kills the norovirus surrogate Feline calicivirus 99.97%!"

[Ex. 20 at 1, 8].

110. After this Court denied Defendant's Motion to Dismiss the action, Heath Harley documented the following disease-specific claim being made about Zylast on zylastdirect.com on March 11, 2019: "Zylast is effective against Influenza 'the flu',

Rhinovirus 'the common cold', E.coli and mor[e]." [Ex. 195 at 1].

111. On March 12, 2019, Heath Harley documented the following disease-specific claims being made about Zylast on zylastdirect.com"

a. information suggesting that Zylast antiseptic provides a 3.5 "Log Reduction" of norovirus;

b. information suggesting that Zylast foaming soap provides "Persistent Reduction of MRSA";

c. "Zylast has been shown in controlled clinical studies to prevent nearly 90% of illness outbreaks in schools and reduce illness absenteeism by 39%";

d. "[w]hen testing was performed against E. coli, the Zylast Foaming Soap was shown to significantly outperform Lysol, CHG, and Lifebuoy soaps, still killing 100% of the transient bacteria 1 hour after the soap was applied and washed off, and 82% after six hours"; and

e. "MRSA is a variation of S. aureus that has mutated to be resistant to a specific strain of antibiotics, but that has no effect on topical antimicrobials. All Zylast products have been tested for immediate kill against S. aureus."

[Ex. 210 at 2; Ex. 212 at 1].

112. Other Zylast marketing sheets created by IBD contained disease-specific claims and falsely suggested that the products complied with FDA regulations. For example:

a. A document titled "Benefits of Zylast in Hospitals" stated that "Zylast is specifically formulated to provide both immediate and persistent kill against drug-resistant bacteria, killing more than 90% of transient MRSA one hour after application." It also stated that the "Zylast products are . . . fully compliant with FDA regulations."

b. Another document titled "Benefits of Zylast for Emergency

Responders" stated that "Zylast has also been shown to kill more than 99% of HIV, influenza, H1N1, Rotavirus, Rhinovirus, Herpes, and others on contact" and "[i]n a study on human skin, Zylast was shown to kill more than 99.99% of E. coli 20 minutes and 1 hour after application." (emphasis in original). It further stated that the "Zylast products are . . . fully compliant with FDA regulations."

[Ex. 133 at 2; Ex. 66 at 1–2; Transcript, Jan. 22, 2020, Vol. IV at 40:10–12, 41:5–18].

113. On September 8, 2019, Heath Harley documented the following disease-specific claims being made about Zylast on zylast.com:

a. "[i]n a study in hospitals, replacing a traditional alcohol sanitizer with Zylast reduced hospital-acquired infections (HAIs) by 20%";

b. "[i]n a clinical study, alcohol-based sanitizers in a long-term care facility were replaced with persistent Zylast Antiseptic. Making this change significantly reduced nosocomial infections";

c. "[i]n the two schools tested, adding Zylast reduced illness absenteeism among students by 39% and among staff by 24%. Even more incredibly, illness outbreaks—when more than 10% of the class was sick—were reduced by nearly 90%"; and

d. "Zylast is the first hand sanitizer to reduce hospital infections in the same trial, showing a reduction of 23.1% in nosocomial infections in a hospital trial of more than 6,000 patients."

[Ex. 172 at 1–2].

**O. When FDA Identified Specific Violative Statements, Defendants Delayed in Removing Them and Sometimes Refused to Remove Them**

114. Defense counsel conducted a Rule 30(b)(6) deposition of Commander Smith, the

Government's representative, on August 30, 2019. During the deposition, Commander Smith provided to Defense counsel a chart of specific statements made by Defendants that were referenced in the Warning Letter, Complaint, Amended Complaint, and the Government's responses to Defendants' first set of interrogatories. [Ex. 549; 12/18/2019 Trans. Vol II at 5:10–5:20; Final Pretrial Conference Order at 3, Dkt. 138].

115. As shown in the chart, between 2015 and August 2019, when FDA provided Defendants with examples of pathogen-specific and infection-prevention claims being made on the Zylast products' labeling, Defendants either refused to remove the statements, modified the statements instead of removing them altogether, or removed the statements months (and sometimes years) after FDA identified them for Defendants. [Ex. 549 at 1, 3, 5, 7, 11, 19, 21, 23, 25, 27, 29, 31, 35].

116. Dr. Cozean testified that she understood FDA viewed each statement listed on the chart to be a disease-specific claim that must be removed from the Zylast products' labeling. This included the following two statements found on zylast.com:

a. "Zylast Foaming Soap showed substantially better persistent effect when tested against both E.coli (gram negative) and MRSA (gram positive) bacteria in testing."

b. "Testimonial . . . Annie Pryor, Ph.D., Stop the Stomach Flu . . . Zylast Antiseptic is a very exciting hand sanitizer that kills the norovirus surrogate feline calicivirus 99.97 percent."

[12/20/2019 Trans. Vol. II at 71:19–72:21].

117. Both statements were and are still being made in the Zylast products' labeling.

a. The first statement—"Zylast Foaming Soap showed substantially better persistent effect when tested against both E.coli (gram negative) and MRSA (gram positive) bacteria in testing"—appeared on zylast.com as of December 19, 2019, and on zylastpro.com

(Defendants' new website) as of January 23, 2020. [Ex. 291-a at 4; Ex. 303 at 18].

b. The second statement—"Zylast Antiseptic is a very exciting hand sanitizer that kills the norovirus surrogate feline calicivirus 99.97 percent"—appeared on zylastpro.com as of January 23, 2020. [Ex. 303 at 24].

**P. Disease-Specific Claims Were Still Being Made on zylast.com During Trial in December 2019**

118. On December 19, 2019, zylast.com contained the claim, "[w]hen compared against other soaps on the market, the Zylast Foaming Soap showed substantially better persistent effect when tested against both E. coli (gram negative) and MRSA (gram positive) bacteria in testing conducted at Pace University." [Ex. 291-a at 4].

119. On December 19, 2019, the homepage of zylast.com contained claims that Zylast could reduce transient E. coli on human skin. [Ex. 291-b at 1].

120. On December 19, 2019, zylast.com contained the claim, "[t]he Zylast Antiseptic is the first hand sanitizer proven to reduce hospital-acquired infection in a controlled, crossover clinical trial." [Ex. 291-a at 3].

**Q. Defendants' Changes to zylast.com and zylastdirect.com, and Their Launch of zylastpro.com**

121. On Tuesday, January 21, 2020—the day before trial was set to resume in this case—Defendants redesigned the zylast.com website. [1/23/2020 Trans. Vol. III at 5:25–6:2].

122. Jesse Cozean testified that zylast.com is now "just a landing page" that "immediately directs you to go somewhere else." [1/22/2020 Trans. Vol. II at 31:3–19].

123. At the top of zylast.com are three boxes: "Customers Only," "Professionals Only,"

and "Contact." [Ex. 292-c at 1]. The box titled "Customers Only" links visitors to zylastdirect.com, where customers can purchase Zylast products such as a "Family Bundle Pack." [*Id.*; Ex. 303a at 1–5; 1/23/2020 Trans. Vol. III at 6:3–6:10].

124. At the top of zylast.com, the box titled "Professionals Only" links visitors to Defendants' new website, zylastpro.com. [Ex. 292-c at 1; 1/23/2020 Trans. Vol. III at 6:13–6:17].

125. Given the absence of substantive information on zylast.com and zylastdirect.com, any customer—healthcare professional or not—interested in learning more about Zylast would have to visit zylastpro.com to get that information. [Ex. 303].

126. The website zylastpro.com contains information, charts, and graphics with disease specific claims regarding the Zylast products. This includes claims, information, charts, and graphics that Defendants knew would not be covered by applicable FDA monographs and which they had previously removed from their websites in response to FDA's concerns. The following appeared on zylastpro.com as of January 23, 2020:

a. "In a study in hospitals, replacing a traditional alcohol sanitizer with Zylast reduced hospital-acquired infections (HAIs) by 20%." [*Id.* at 2; *see also* Ex. 549 at 19–20 (identifying this claim as evidence of the Zylast products' unapproved new drug status)].

b. "In a clinical study, alcohol-based sanitizers in a long-term care facility were replaced with persistent Zylast Antiseptic. Making this change significantly reduced nosocomial infections." [Ex. 303 at 3; *see also* Ex. 549 at 20 (identifying this claim as evidence of the Zylast products' unapproved new drug status)].

c. "In a historically controlled clinical trial at a 325 bed hospital over three years . . . the hospital showed a statistically significant reduction overall [in] hospital acquire [sic] infections (0%), C. difficile (28%), and VRE (40%) and a reduction in MRSA (14%)" when using the

Zylast Antiseptic Lotion and Zylast Antiseptic Foaming Soap. [Ex. 303 at 8; *see also* Ex. 549 at 23 (identifying this claim as evidence of the Zylast products' unapproved new drug status)].

d. "[T]he Zylast Foaming Soap showed substantially better persistent effect when tested against both E. coli (gram negative) and MRSA (gram positive) bacteria in testing conducted at Pace University." [Ex. 303 at 18; *see also* Ex. 549 at 25 (identifying this claim as evidence of the Zylast products' unapproved new drug status)].

e. "Zylast Antiseptic is a very exciting new hand sanitizer that kills the norovirus surrogate Feline calicivirus 99.97%!" [Ex. 303 at 24; *see also* Ex. 549 at 25 (identifying this claim as evidence of the Zylast products' unapproved new drug status)].

f. A chart claiming that Zylast provides persistent reduction of MRSA at 2 minutes, 1 hour, and 6 hours after application. [Ex. 303 at 11]. A nearly identical chart previously appeared on zylastdirect.com on May 8, 2018 and March 12, 2019, but Defendants removed it sometime before August 30, 2019. [Ex. 199 at 2; Ex. 212 at 2; 1/23/2020 Trans. Vol. III at 31:5–32:4].

g. A chart claiming that Zylast reduces the amount of transient E. coli on human skin, 20 minutes, 1 hour, and 6 hours after application. [Ex. 303 at 3]. A nearly identical chart previously appeared on zylast.com on December 20, 2019. [Ex. 291-b at 1].

h. "In the two schools tested, adding Zylast reduced illness absenteeism among students by 39% and among staff by 24%. Even more incredibly, illness outbreaks—when more than 10% of the class was sick—were reduced by nearly 90%." [Ex. 303 at 5].

i. "Zylast is the first hand sanitizer to reduce hospital infections in the

same trial, showing a reduction of 23.1% in nosocomial infections in a hospital trial of more than 6,000 patients." [Ex. 303 at 8].

j. "[T]he Zylast Antiseptic was shown to kill 99.97% of the norovirus surrogate on human skin at contact." [Ex. 303 at 12].

k. "The Zylast Antiseptic is the first hand sanitizer proven to reduce hospital acquired infection in a controlled, crossover trial." [Ex. 303 at 16].

127. As illustrated by the facts above, while Defendants previously removed certain disease specific claims from zylast.com and zylastdirect.com, they republished those and added other disease-specific claims on zylastpro.com.

**R. Defendants Continue to Violate the FDCA by Introducing or Causing the Introduction of Unapproved New Drugs in Interstate Commerce**

128. Despite the Court's holding at summary judgment that IBD, Dr. Cozean, and Hotan Barough violated the FDCA as a matter of law by introducing, or causing the introduction of, the Zylast products into interstate commerce [Order Granting in Part Pl.'s Mot. for Summ. J. & Den. Def.'s Mot. for Summ. J. at 13–14, Dkt. No. 124] Hotan Barough testified at trial that he continues to fulfill orders of Zylast. [1/23/2020 Trans. Vol. II at 58:2–6].

## II. CONCLUSIONS OF LAW

129. In its summary judgment ruling, the Court held that Defendants violated the FDCA as a matter of law. [Order Granting in Part Pl.'s Mot. for Summ. J. & Den. Def.'s Mot. for Summ. J. at 14, Dkt. 124]. Accordingly, the only issues that were left to be addressed at trial were Defendants' affirmative defenses of laches and unclean hands and the appropriate scope of injunctive relief. [*Id*. at 18, 18 n.6].

**A. Defendants' Affirmative Defenses**

130. The law presumes that the Government and its employees properly exercise its enforcement authority. This presumption can be rebutted only with "clear evidence." *United States v. Chemical Factory*, 272 U.S. 1, 15 (1926); *see also Red Top Mercury Mines v. United States*, 887 F.2d 198, 202–03 (9th Cir. 1989) (describing the "presumption of regularity").

*Laches*

131. The presumption against the applicability of laches in a suit brought by the United States is stronger when the Government brings suit to protect the public interest. *See, e.g.*, *INS v. Hibi*, 414 U.S. 5, 8 (1973); *United States v. Ruby Co.*, 588 F.2d 697, 705 n.10 (9th Cir. 1978); *SEC v. Gold Standard Mining Corp.*, No. CV 12-5662 PA (CWX), 2012 WL 12904080, at *2 (C.D. Cal. Dec. 10, 2012).

132. In order to prevail under this defense, Defendants would have to prove, with clear evidence, that the Government engaged in affirmative misconduct. *Ruby*, 588 F.2d at 705 n.10. Only if Defendants are able to satisfy this threshold burden may the Court consider whether Defendants also have satisfied the two required elements of laches. *Id*.

133. The Court finds that the Government did not engage in affirmative misconduct and therefore the Defendants cannot prevail on a laches defense.

134. First, there is no clear evidence that the FDA disclosed information about the Warning Letter to GOJO before the letter was issued to IBD. Further, the FDA had no legal obligation to warn any of the Defendants that they were in violation of the FDCA prior to issuing a Warning Letter or even filing suit. *United States v. Carlson*, No. CRIM. 12-305-DSD/LIB, 2013 WL 5125434, at *5 (D. Minn. Sept. 12, 2013).

135. Even if misconduct was proven by clear evidence, the Court finds that Defendants suffered no prejudice as a result of the Government filing suit on June 6, 2018:

a. First, there is no clear evidence that the Government's timing in filing

suit resulted in an "inability [by Defendants] to present a full and fair defense on the merits.'" *Id.* at 1072 (quoting *Freeman v. Gerber Prods. Co.*, 466 F. Supp. 2d 1242, 1246 (D. Kan. 2006)).

b. Further, Defendants did not rely in any way on the absence of a lawsuit by the Government. *See Eat Right Foods Ltd. v. Whole Foods Mkt., Inc.*, 880 F.3d 1109, 1119 (9th Cir. 2018).

136. The facts and issues Defendants argue Dr. Brullo failed to recall due to the length of time between the issuance of the Warning Letter and his deposition are insignificant at best and did not deter their ability to present a full and fair defense.

137. Thus, Defendants have not carried their burden of proof on their affirmative defense of laches.

*Unclean Hands*

138. Bad intent is the essence of the defense of unclean hands. Accidental, inadvertent, or even grossly negligent behavior by itself does not suffice. *See Dollar Sys. v. Avcar Leasing Sys.*, 890 F.2d 165, 173 (9th Cir. 1989).

139. In order to prevail on this defense, Defendants must prove, via clear evidence, that the Government engaged in outrageous conduct that caused constitutional injury. *Perez v. West Coast Drywall & Co., Inc.*, No. CV 16- 01565-BRO (SPx), 2016 WL 11002590, at *4 (C.D. Cal. Nov. 10, 2016). This would generally require Defendants to show that the Government's decision to commence litigation lacked a rational relationship to any legitimate state interest. *Id.*; *Pusateri v. Klamath Cty. Cmty. Dev.*, No. 1:18-CV-00058-MC, 2018 WL 468300, at *3 (D. Or. Jan. 18, 2018).

140. However, the Court finds that the Government did not engage in outrageous conduct by enforcing the FDCA against the Defendants. Further, the Government did not engage in conduct that caused Defendants to suffer any constitutional injury. There was no pretext for enforcing the FDCA against the Defendants for any impermissible motive.

141. Thus, Defendants have not met their burden of proof on their affirmative defense of unclean hands.

*Injunctive Relief*

142. Injunctive relief is appropriate if there is "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953).

143. Given the Court's ruling at summary judgment that "Defendants violated the [FDCA] as a matter of law," there exists an inference that Defendants are likely to violate the FDCA again in the future. Order Granting in Part Pl.'s Mot. for Summ. J. & Den. Defs.' Mot. for Summ. J. at 14.

144. To overcome this inference, Defendants bear the burden of proving that "there is no reasonable expectation that [their violations of the FDCA] will be repeated." *W.T. Grant Co.*, 345 U.S. at 633.

145. In determining whether there exists a cognizable danger of recurrent violation by Defendants, the Court also may consider the degree of scienter involved; the isolated or recurrent nature of Defendants' violations; whether Defendants recognize the wrongful nature of their conduct; the extent to which Defendants' professional and personal characteristics might enable or tempt them to commit future violations; and the sincerity of any assurances against future violations. Order Den. Mot. to Dismiss at 5 (quoting *United States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 854–55 (9th Cir. 1995)), Dkt. 82. Each factor supports the issuance of broad injunctive relief in this case.

146. Defendants' violations of the FDCA are persistent and recurrent in nature.

    a. There is no dispute that, for years, Defendants suggested the Zylast products for use in preventing illness and infection by specific pathogens like MRSA, norovirus, HIV, herpes, and Ebola. Order Granting in Part Pl.'s Mot. for Summ. J. & Den. Defs.' Mot. for Summ. J. at 7, n.2. Because the products are not generally recognized

as safe and effective for all of those intended uses, *id.* at 13, Defendants violated the FDCA on a persistent and ongoing basis by introducing, or causing the introduction of, unapproved new drugs into interstate commerce.

147. Defendants' assurances that they will not violate the FDCA in the future are not credible.

148. Injunctive relief is warranted due to Defendants' repeated and continuing violations of the FDCA, despite receiving notice on multiple occasions from FDA and this Court that they are unlawfully introducing unapproved new drugs into interstate commerce.

149. Defendants ask the Court to delay the injunction pending the FDA issuing further guidance on pathogen-specific statements and pending FDA enforcement against other companies currently making those statements.

150. The Court finds that it is not proper to delay a necessary injunction pending further action from the FDA. Indeed, the FDA holds considerable discretion in making decisions on whether and how to use resources to enforce the FDCA. However, as this Court has already made clear, the circumstances surrounding the lack of enforcement against GOJO Industries is troubling, and the Court is of the opinion that the disparities in enforcement should be addressed expeditiously.

151. The Court notes without providing comment that, after the issuance of a warning letter against GOJO Industries by the FDA during this trial, a class-action consumer protection suit was filed in the Northern District of Ohio on March 13, 2020. *See Miller et al. v. GOJO Industries, Inc.*, 4:20-cv-00562.

152. Whether or not such a lawsuit is meritorious, it is clear that FDA enforcement actions are an important part of public health and safety. Thus, it is imperative that such enforcement is done in a consistent manner.

153. The Court will issue its formal injunctive order separately.

## IV. CONCLUSION

After considering the parties' arguments, for the reasons explained above, the Court **HOLDS** that Defendants have not met their burden on any of their affirmative defenses. The Court also **HOLDS** that injunctive relief is appropriate. The Court **DENIES AS MOOT** Defendants' Motion for Reconsideration [Dkt. 145]. The Parties shall submit a joint proposed judgment in accordance with this Court's ruling **on or before May 15, 2020.**

DATED: May 4, 2020

DAVID O. CARTER
UNITED STATES DISTRICT JUDGE